PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6:

G06F 19/00

A1

(11) International Publication Number: WO 95/06296

(43) International Publication Date: 2 March 1995 (02.03.95)

(21) International Application Number: PCT/US94/09417

(22) International Filing Date: 25 August 1994 (25.08.94)

(30) Priority Data:

08/112,456

27 August 1993 (27.08.93)

US

(71) Applicant: TALISMAN, LTD. [US/US]; Suite 435, 7600-B Leesburg Pike, Falls Church, VA 22043 (US).

(72) Inventors: CUMMING, Paul, D.; 1740 Burning Tree Drive, Vienna, VA 22182 (US). KARPF, Ronald, S.; 11425 Brandy Hole Lane, Gaithersburg, MD 20878 (US).

(74) Agents: PATTERSON, Herbert, W. et al.; Finnegan, Henderson, Farabow, Garrett & Dunner, Suite 700, 1300 I Street N.W., Washington, DC 20005-3315 (US).

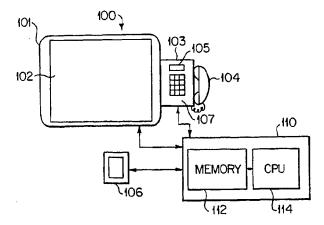
(81) Designated States: AM, AT, AU, BB, BG, BR, BY, CH, CN, CZ, DE, DK, EE, ES, FI, GB, GE, HU, JP, KE, KG, KP, KR, KZ, LK, LT, LU, LV, MD, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SI, SK, TJ, TT, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG), ARIPO patent (KE, MW, SD).

Published

With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: AUTOMATED SYSTEM AND METHOD FOR ELICITING CONFIDENTIAL INFORMATION FROM A PATIENT



(57) Abstract

an automated computer system using audio and visual material for posing and recording answers to highly confidential questions to respondents. The system allows a respondent to tune the system to his own sense of privacy through the choice of alternate audio devices a speaker or a more private handset; volume controls; choosing to view the questions and supporting pictorial materials or to more privately hide them from view; choosing whether to have verbal feedback of their responses; and choosing the touchscreen response buttons or a more privately held touchpad. The questions are available in multiple languages (English, Spanish, and others), and the sequence of questions is customized for the sex of the respondent and their new/repeat status. The questions are mutually reinforced through three sets of materials - audio, text and visual, to maximize comprehension. Respondents' access to response buttons is delayed until such a time that they have heard or read sufficient materials to understand the question. The sequence and content of questions is controlled through an input file which can be easily modified. As the questioning process proceeds each response and indirect information about each response are recorded so decision rules more complicated than just right/wrong answer can be implemented.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria .	Œ	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic	SD	Sudan
CG	Congo		of Korea	SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	Prance	MN	Mongolia	VN	Viet Nam
GA	Gabon		. •		

- 1 -

AUTOMATED SYSTEM AND METHOD FOR ELICITING CONFIDENTIAL INFORMATION FROM A PATIENT Background of the Invention

This invention relates to a system for eliciting confidential information, and more specifically to a system for eliciting confidential medical histories and information from human beings.

5

10

15

20

25

In certain activities, such as screening blood or plasma donors, taking medical histories from patients, or employment interviews, it is sometimes necessary to pose questions of a personal or confidential nature. Because a respondent's answers may affect his qualifications to donate blood or plasma or the selection of appropriate medical procedures for his condition or may subject an employer to litigation, it is important that the respondent provide accurate and complete responses. example, units of whole blood, red cells, platelets, and plasma, (collectively "blood components") necessary to sustain life in surgical procedures and used to manufacture lifesaving pharmaceuticals can pose a significant risk to the recipients of the blood components or pharmaceuticals if prior donor behavior and medical conditions are not properly addressed as a qualification for donating. Similarly, a patient must provide truthful answers to questions about medical history if an attending physician is to provide appropriate medical treatment. Hiring or retaining an employee using illegal drugs can result in work place accidents and other deleterious effects.

Unfortunately, simply posing a battery of questions to a donor, patient, or potential employee is not the best way to elicit wholly truthful and accurate responses.

Because the questioner must ask questions of a confidential nature, e.g., questions about illegal drug use, sexual practices, income, religion, etc., and because the questioning is performed in an environment which may invade a respondent's sense of privacy, a respondent may

- 2 -

not always be completely candid with his answers. the questionnaire environment is uncomfortable not only for the respondent but also for the questioner, and questions may be improperly posed, or posed in a manner perceived by the respondent as threatening.

Lack of comprehension by the respondent is also a problem, especially if the respondent has a poor command of English, or if the respondent perceives the questions as boring. When the respondent is using a paper form, there is not even any assurance that the questions have been completely read.

5

10

15

20

25

30

35

In addition, transcription errors may occur when responses are recorded by a human interviewer or key entry errors may occur when responses are entered into a computer database. Additionally, interviewer bias may affect the responses. The interviewer may also fail to ask all requisite questions. These errors and omissions can lead to citations from the U.S. Food and Drug Administration (FDA) and possible loss of an establishment's license to collect and distribute blood products. These errors may also subject the establishment to lawsuits. Finally, after the questioning is finished, there may be indirect information that would be useful in making a medical decision. For example, if only a Yes/No response is elicited, other available information, such as consistency with answers given during a prior session, whether the respondent answered and then changed his response, and a length of time the respondent spent considering the question may also be reasonable criteria to consider.

Summary of the Invention

The present invention overcomes the problems and disadvantages of the prior art by giving the respondent a number of options customizing the manner in which questions are posed and/or answered and assuring that all questions are addressed and responses recorded correctly. In accordance with the respondent's preference, the

- 3 -

questions may be asked so that the questions are audible only to the respondent and are not visible to other persons who may be present. Similarly, the respondent may, at his option, give his responses in a way that does not make them visible to other persons during the questioning session. The respondent also controls the volume of any audible output and may choose to suppress an audible echo of his responses. Allowing the respondent to select various options to ensure the confidentiality of his responses results in the respondent giving more accurate, complete, and truthful information.

5

10

15

20

25

30

35

The invention facilitates correct responses by improved communication because each question is displayed on a display screen, asked via audio, and illustrated with color pictures and graphics. The questions are presented consistently each time, thus controlling interviewer bias. The invention also eliminates transcription and key entry errors and the questions are stored in a manner that makes them easy to update.

In addition, the present invention overcomes the problems and disadvantages of the prior art by allowing the respondent to choose the language in which the questions are asked both audibly and displayed on the screen. The invention also waits a predetermined time before accepting input from the respondent, to ensure that the respondent has had time to read or hear the question. Lastly, the invention keeps track of indirect information about responses, such as consistency with prior answers, whether the respondent answered then changed their response, and a length of time the respondent spent considering the question.

In accordance with the purpose of the invention, as embodied and broadly described herein, the invention is a system for gathering confidential data from a human respondent, comprising: a display device; means for presenting the human respondent with two privacy alternatives that relate to a manner in which a response

- 4 -

should be solicited; means for receiving an input from the human respondent choosing one of the privacy alternatives; means for soliciting, via the display device in accordance with the chosen privacy alternative, the response; and means for receiving a response from the human respondent.

5

10

15

20

25

30

35

In accordance with the purpose of the invention, as embodied and broadly described herein, the invention is a system for gathering confidential data from a human respondent, comprising: an audio output device; means for allowing the human respondent to control the volume of the audio output device; means for presenting the human respondent with two privacy alternatives that relate to a manner in which a response should be solicited; means for receiving an input from the human respondent choosing one of the privacy alternatives; means for soliciting, via the output device in accordance with the chosen privacy alternative, the response; and means for receiving the response from the respondent.

In accordance with the purpose of the invention, as embodied and broadly described herein, the invention is a system for gathering confidential data from a human respondent, comprising: a first input device; a second input device; means for displaying two privacy alternatives that relate to the first and second input devices; means for receiving an input from the human respondent choosing one of the privacy alternatives; means for soliciting a response from the human respondent; and means for receiving a response from the human respondent via one of the first and second input devices in accordance with the chosen privacy alternative.

In accordance with the purpose of the invention, as embodied and broadly described herein, the invention is a system for gathering confidential data from a human respondent, comprising: an audio output device; means for receiving an input from the human respondent indicating a desired degree of privacy during questioning; means for soliciting the human respondent for a response; means for

10

15

20

25

receiving a response from the human respondent; and means for echoing the response via the audio output device when the human respondent indicates a predetermined degree of privacy.

In accordance with the purpose of the invention, as embodied and broadly described herein, the invention is a system for gathering confidential data from a human respondent, comprising: an audio output device having a hands et and a loudspeaker; means for allowing the respondent to indicate a privacy alternative relating to whether a response is solicited via the handset or the loudspeaker; means for soliciting, via the audio output device in accordance with the indicated privacy alternative, the response; and means for receiving a response from the human respondent.

Objects and advantages of the invention will be set forth in part in the description which follows and in part will be obvious from the description or may be learned by practice of the invention. The objects and advantages of the invention will be realized and attained by means of the elements and combinations particularly pointed out in the appended claims.

Brief Description of the Drawings

The accompanying drawings, which are incorporated in and constitute a part of this specification, illustrate several embodiments of the invention and, together with the description, serve to explain the principles of the invention.

- Fig. 1 is a block diagram of a preferred embodiment 30 of the present invention;
 - Fig. 2 shows an example format of a question screen displayed on a touchscreen of Fig. 1;
 - Fig. 3 shows an example of a question screen having the format of Fig. 2;
- Fig. 4 is a picture of a touchpad of Fig. 1 with a template laid over it;

PCT/US94/09417

WO 95/06296

- 6 -

Fig. 5 shows an example of a display screen on a touchscreen of Fig 1;

- Fig. 6 shows an example of a display screen on the touchscreen of Fig. 1;
- Fig. 7 shows an example of a display screen on the 5 touchscreen of Fig. 1;
 - Fig. 8 shows an example of a display screen on the touchscreen of Fig. 1;
- Fig. 9 is a flowchart of a steps performed by a 10 processor of Fig. 1;
 - Fig. 10 is a flowchart of a steps performed by a processor of Fig. 1;
 - Fig. 11 shows a format of data stored after a set of questions has been asked;
- 15 Fig. 12(a) shows a format of a data structure used to implement a state machine indicating an order of questions and a screen format for each question; and
 - Fig. 12(b) shows a table of the data structure of Fig. 12(a).
- 20 <u>Detailed Description of the Preferred Embodiments</u> Reference will now be made in detail to the preferred embodiments of the invention, examples of which are illustrated in the accompanying drawings. Wherever possible, the same reference numbers will be used 25 throughout the drawings to refer to the same or like parts.

Overview

30

To solve the problems of conventional systems, the present invention allows respondents to answer questions based on their own sense of privacy in a language of their choice. The questions are customized to the sex of the respondent and other factors, such as whether the respondent has heard the questions before.

The respondent can tune the system to achieve his 35 sense of privacy through volume controls, source of the audio (loudspeaker or handsets), whether to have verbal feedback of a response, and controlling the visibility of

10

15

20

25

30

35

text and graphics on the screen that could provide any hint as to the nature of the questions to other persons present. The respondent also controls the input source, using, e.g., a touchscreen or a more confidential touchpad device.

Depending on the alternatives chosen by the respondent, the audio of each question is accompanied by a display of full text of the question and by color graphics, which mutually reinforce each other and serve to hold the attention of the respondent. To keep the respondent from answering questions before they are finished, response buttons are not activated until after a predetermined period of time. The sequence and content of questions is controlled by entries in an input setup file that is easily edited to change the text, color graphics, or question order. Responses are collected and used as input to a general respondent qualification decision rule. The decision rule is stored in a file or table and may be easily changed. The responses or decision result may be output to a printer or CRT for aiding human decision making.

II. A Blood Donor Screening System

A blood donor is defined as any person who donates, either freely or for compensation, whole blood or any whole blood component, e.g., red cells, platelets or plasma.

(A) Hardware

Fig. 1 is a block diagram of a preferred embodiment of the present invention. A system 100 of Fig. 1 is used to elicit confidential information from potential blood donors, but could also be used to elicit confidential information of other types, such as information relating to medical histories, employment or welfare eligibility. System 100 of Fig. 1 includes a monitor 101 having a touch screen 102 and a speaker unit 103. Speaker unit 103 includes a thumbnail switch volume control 105, a handset 104, and a loudspeaker 107. System 100 also includes—a

30

35

touchpad 106 connected to computer 110. Computer 110 includes a memory 112 and a processor (CPU) 114. Monitor 101 is connected to computer 110 in a manner known to persons of ordinary skill in the art. Other embodiments may use, e.g., a mouse keyboard, stylus, bar code magstripe reader, or a Braille touchpad as an input device instead of touchscreen 102, and may use, e.g., a headset or earphones as an audio output device instead of handset 104.

In the described embodiment, a question is always 10 output verbally through speaker unit 103 using one of handset 104 and loudspeaker 107. Speaker unit 103 is connected to computer 110. In the described embodiment, the question is output over loudspeaker 107 when handset 104 is in its cradle. When handset 104 is picked up, the 15 question is output over handset 104, and not over loudspeaker 107. Thus, if the respondent does not want the questions to be audible to other persons, he picks up handset 104, and the questions cannot be heard by others. The determination of whether handset 104 is in its cradle 20 preferably is made by circuitry internal to speaker unit In the described embodiment, the respondent can adjust the volume of both loudspeaker 107 and handset 104 to a level that the respondent feels is both comfortable 25 and confidential using volume control 105. Computer 110 sends signals to speaker unit 103 to control audio output and may receive status signals from speaker unit 103.

Computer 110 preferably is a Compudyne 486 PC manufactured by Compudyne Corp. of Addison, Texas.

Touchscreen 102, which attaches to the front of a standard computer monitor, preferably is a TouchWindow, manufactured by Edmark, Inc. of Redmond, Washington.

Touchpad 106 preferably is an UnMouse manufactured by MicroTouch, Inc. of Wilmington, Massachusetts. Speaker unit 103 preferably is a Sound XChange unit, manufactured by InterActive, Inc. of Humboldt, South Dakota.

15

20

25

30

35

In the described embodiment, computer 110 is executing under MS-DOS 5.0 running Microsoft Windows 3.1 with multimedia extensions. The questions are input and displayed under a computer program written in a computer language called "Asymetrix Toolbook 1.5," produced by Asymetrix Corp. of Bellevue, Washington. Questions and responses are stored in a database using Dbase IV, produced by Borland Corp. of Scotts Valley, California. Other embodiments may use other hardware and software components.

Fig. 2 shows an example format of a question screen 200 displayed on touchscreen 102. Screen 200 includes a number of windows, or fields, generated using Microsoft Field 202 preferably shows a still photograph of a nurse. Field 202 is included to "humanize" the display and may be omitted in other embodiments. Field 204 preferably shows the text of a question. Field 204 may also be blank, as described below. Field 206 preferably shows a color graphic associated with the question. Field 206 may also be blank, as described below. In addition, screen 200 includes a title field 207, which contains a title of a type of screen 200 (e.g., "Medical History"); a label field 208, which contains a label of the question (e.g., "Question 1"); and an answer field 209, in which the respondent's current answer is echoed. The respondent may change his answer at any time that the screen is displayed, and may go back to any screen to change his answer.

Screen 200 includes a plurality of buttons 210.

Buttons 210 include a "Back" button, a "Yes" button, a
"Don't Know" button, a "No" button, and a "Next" button.

The "Back" button indicates that the respondent wants to display a previous question. The "Yes" button, the "No" button, and the "Don't know" button each represent a possible response to a question. The "Next" button indicates that the respondent wishes to go to the next question. In the described embodiment, it is possible to

10

15

20

25

30

35

skip a question by touching the "Next" button. Other embodiments may not allow N questions to be skipped, may have different buttons such as VCR-like buttons to control motion video, mutually exclusive choices of year buttons to indicate when respondent traveled outside the U.S., or different arrangements of the described buttons.

Fig. 3 shows an example of a question screen 300 displayed on touchscreen 102 and having the format of screen 200 of Fig. 2. Field 307 preferably shows the title of the screen ("Medical History"). Field 302 preferably shows a still color photograph of a nurse. Field 304 preferably shows the text of a question (e.g., "Have you read and do you understand the required information about AIDS and associated risk factors? Do you understand the blood donation process?") Field 306 preferably shows a color graphic associated with the question. Field 308 shows a label associated with the question ("Question 1"). Field 309 will contain an echo of a button touched by the respondent. Preferably, the question is also spoken over speaker unit 103. If handset 104 in speaker unit 103 is not picked up, the question is spoken over loudspeaker 107 in speaker unit 103. handset 104 is picked up, the question is spoken over handset 104. When the respondent touches a button, the button is echoed audibly over speaker unit 103 and visually in field 309 (unless the respondent has disabled the echo function).

Fig. 4 is a picture of touchpad 106 with a template laid over it. The template has printed buttons 410 similar to buttons 210 of Fig. 2. Various sections of touchpad 106 correspond to buttons 410 and touching those sections of touchpad 106 (when touchpad 106 is enabled) has the same effect as touching buttons 210 on touchscreen 102. Other embodiments of the invention may include different or additional buttons on touchpad 106, e.g., buttons similar to those discussed below in connection with Figs. 5 and 6.

- 11 -

(B) Privacy Option

Initially, during operation of the system of Fig. 1, but before questions of a confidential nature have been asked, questions controlling a degree of user privacy and 5 other options, such as language choice, are displayed on touchscreen 102. In the described embodiment, the respondent is given a choice between two "privacy alternatives" for each privacy option. Fig. 5 shows an example of a display screen 500 on touchscreen 102. 10 Display screen 500 has four fields: a "language" field 502, a "question text and pictures" field 504, a "repeat response verbally" field 506, and an "answer questions with" field 508. Screen 500 also has a "continue" button 512, which indicates that the respondent wants to go to a 15 next screen. Each field 502-508 allows the respondent to select one of a plurality of alternatives for a privacy The respondent selects an alternative by touching the screen, or by using a mouse (not shown), touchpad 106, or some similar pointing/selection device.

Language field 502 allows the respondent to select the alternative of having questions displayed and/or spoken in English or Spanish. The question displayed in field 202 of Fig. 2 is displayed in either English or Spanish and the question is output to speaker unit 103.

Other embodiments of the invention may allow the respondent to choose other languages. Field 502 preferably N defaults to "English."

Fields 504-508 allow the user to select other alternatives that control the degree of privacy for the session. Field 504 allows the respondent to select whether text and graphics associated with each question are displayed on touchscreen 102. If the respondent does not wish potentially embarrassing text or graphics to be displayed, he selects "not shown." Field 504 preferably defaults to "visible."

30

35

Field 506 allows the respondent to select whether his responses are echoed (in field 209 of Fig. 2 and through

- 12 -

speaker unit 103) or are not echoed. If the respondent does not wish potentially embarrassing responses to be echoed, he selects "off" and his responses are not echoed either audibly or on touchscreen 102. Field 506 preferably defaults to "on."

5

10

15

20

25

30

35

Field 508 allows the respondent to select either touchscreen 102 or touchpad 106 as the input device when responding to confidential questions. If the respondent does not want other persons to see him making responses (as would happen with touchscreen 102), he selects "Private Touchpad" for touchpad 106. Field 508 preferably defaults to "touchscreen."

In the described embodiment, at any time during the session, the respondent can toggle the "visible"/"not shown" option. This option is toggled by touching any part of the text or graphic display on touchscreen 102. For example, if the text and graphics are displayed ("visible" mode), touching the text or the graphic will cause the system to enter "not shown" mode, and the text and graphics will be erased from touchscreen 102. The words "Touch Here to View the Question" appear in the text box 204 of screen 200. Touching these words toggle the "visible" option on.

In the embodiment of Fig. 1, at any time during the confidential questioning, the respondent can toggle the "touchscreen"/"private touchpad" option. This option is toggled by touching the desired input device. example, if the respondent is using buttons 210 to indicate his responses, touching touchpad 106 will cause the system to accept input from touchpad 106, and not display the buttons 210 on the screen. Touching touchscreen 102 again will cause buttons 210 to be displayed again, and input to be accepted from buttons 210 of touchscreen 102. Other embodiments may also allow simultaneous input from both input devices. described embodiment, other privacy options cannot be toggled. Other embodiments may differ.

Fig. 6 shows an example of a display screen 600 on touchscreen 102. Display screen 600 has two fields: a "sex" field 602, and a "donation status" field 604. Each field 602 and 604 allows the respondent to select one of a plurality of options. Field 602 allows the respondent to indicate his or her sex. Field 602 preferably defaults to "male." Field 604 allows the respondent to indicate whether he is a new donor or a repeat donor. Field 604 preferably defaults to "new donor."

5

10

15

20

25

30

35

When the respondent selects "visible" in field 504 of Fig. 5 ("visible"/"not shown"), a screen such as that of Fig. 3 is displayed. When the respondent selects "not shown", however, a screen such as that of Fig. 7 is displayed for each question. Fig. 7 is similar to Fig. 2, except that field 706 is blank and field 704 contains the words "Touch Here to View the Question."

When the respondent selects "touchscreen" in field 508 of Fig. 5 ("touchscreen"/"private touchpad"), a screen such as that of Fig. 2 is displayed. When the respondent selects "private touchpad", however, a screen such as that of Fig. 8 is displayed for each question. Fig. 8 is similar to Fig. 3, except that buttons 210 are not displayed. Since the user will be indicating responses on touchpad 106 (see Fig. 4), for privacy, the responses are not displayed on touchscreen 102.

When the respondent selects both "private touchpad" in field 508 and "not shown" in field 504 of Fig. 5, a screen (not shown) that is similar to Fig. 7 but that does not have buttons 710 is displayed. Since the user will be indicating responses on touchpad 106, there is no purpose in displaying buttons on touchscreen 102. Since the respondent desires a high degree of privacy, the text and color graphics are not displayed on touchscreen 102.

(C) Asking Questions

Fig. 9 is a flowchart of the steps performed by processor 114 of Fig. 1 executing a program stored in memory 112 during the operation of the described

15

20

25

30

35

embodiment for blood donor screening. In step 902, processor 114 displays the screen of Fig. 5 on touchscreen 102 and allows the respondent to enter his or her privacy options and language choices. The respondent may select different alternatives for the various options until he finalizes his options by touching "continue" button 512, which is verbally echoed. The respondent's choices are stored by processor 114 in memory 112 or in some other storage medium, such as a hard disk (not shown). Throughout this document, the term "storage medium" is also intended to include, e.g., an optical and/or a CD ROM storage device.

In step 904, processor 114 displays the screen of Fig. 6 on touchscreen 102 and allows the respondent to indicate his or her sex and whether he is a repeat donor. The respondent finalizes his entry by touching "continue" button 612, which is verbally echoed. Other embodiments may request that the respondent enter a social security number, use a bar code or magstripe identification card, or have their picture or signature recorded (not shown).

In steps 906-912, processor 114 displays screens having a format of Fig. 2 on touchscreen 102 (or Fig. 7 or Fig. 8, depending on the privacy options entered) and allows the respondent to enter his response to questions 1 through n. The steps performed to ask a question and receive a response are described in connection with Fig. 10. Fig. 9 shows a path between step 908 and 906 to indicate that a previous question is asked when the "Back" button is touched.

In step 914, after all questions have been asked, processor 114 applies a decision rule to decide if the respondent will be allowed to donate blood. Other embodiments may output the information for human decision making via printer or monitor instead of, or in addition to, the decision rule. This decision rule is discussed below. If the result of the decision rule is "yes," the respondent is allowed to donate blood and a message to

- 15 -

that effect is displayed on touchscreen 102. If the result of the decision rule is "no," the respondent is deferred and is not allowed to donate blood. A message to that effect is displayed on touchscreen 102. These messages are displayed whether or not the "not shown" option is turned on. In step 920, processor 114 saves the donor's status in memory 112 or in some other storage device, such as a hard disk, along with a social security number or other unique ID, and/or outputs results to a printer or another CRT.

In the described embodiment, an answer of "yes" to certain questions (e.g., "Have you ever had an AIDS (HIV) test that was positive?") will cause the respondent to be deferred as a donor. Other embodiments may use more sophisticated decision rules. For example, the following decision rule applies to a system where some questions should be answered "Yes" and some should be answered "No" and the system stores previous responses from previous sessions of each donor in a database. The current set of questions and answers are Session, The previous set of questions and answers are Session n-1.

If $Session_{n-1}$ is on file then

If any answer from a current $Session_n$ is inconsistent with a previous answer from $Session_{n-1}$ then

Disqualify the donor

Else If each answer is consistent then

If all answers match a predetermined set

of answers then

Qualify the donor

Else

10

15

20

25

30

35

Disqualify the donor

Else (Session_{n-1} is not on file)

If all answers match a predetermined set of answers then

Qualify the donor

- 16 -

Else

Disqualify the donor

In some embodiments, the database may be stored in a memory of a computer at a central location, and processor 114 accesses the central computer's database via modem or a network. In other embodiments, the database may be stored in memory 112 or in a storage device of computer 110.

10

15

25

30

5

The following is another example of a possible decision rule:

If the respondent took more than one minute to answer any question then

Disqualify the donor

Else

Qualify the donor

The following is another example of a decision rule used in a medical history taking application:

- 1. Look up respondent (or respondent ID) in a database.
 - 2. If respondent is in the database then If respondent has been identified as a litigation risk then

Follow Doctor/Patient appointment procedure A

Else

Follow Doctor/Patient appointment procedure B

Else

If respondent is not in the database then follow Doctor/Patient appointment procedure C

35

The following is another example of a decision rule where processor 114 solicits and receives from the

- 17 -

respondent a time since respondent's last donation. The system also solicits and receives a type of donation occurring (or a type of donation is pre defined).

5

If time since last donation < minimum acceptable time for this type of donation Disqualify the donor

Else

Qualify the donor

10

15

20

25

30

35

A type of donation occurring determines the minimum acceptable period of time between donations. For example, homologous whole blood donors may donate approximately every eight weeks. Autologous donors may donate as often as once a week. Platelet donors may donate more frequently than whole blood donors, e.g., on the order of every two weeks. The minimum acceptable periods of time are stored in memory 112 or are stored in a database of a central computer system and accessed by processor 114 via modem or network connections. In other embodiments processor 114 may access a database to determine a time since last donation instead of eliciting this information from the respondent.

The result of the decision rule preferably is saved in memory 112. In other embodiments the result may also be saved an disk, in a central database, presented to a medical professional via CRT for additional review, or output to a printer as permanent legal record or for other purposes. Certain embodiments, such as those regulated by the FDA, will always print out or display a summary of all decisions and the data used to reach the decision, so that a human operator can verify the decision. Such a system may allow the reviewer to store notes on why a donor was or was not allowed to donate and to store a signature of the reviewer and/or donor. Other embodiments may not have provisions for human oversight.

10

15

20

25

30

35

The following paragraphs describe steps performed by processor 114 to ask one question. All of the steps of Fig. 10 are performed once for each of steps 906-912 of Fig. 9. In step 1002, processor 114 initializes variables representing an initial start time and an initial question number. The initial start time is also saved in a memory or other storage device. In step 1004, if a current question should be skipped because of the donor's sex, processor 114 sets a button (BTN) variable to "skip" in step 1006 and control passes to step 1022. (The respondent previously indicated his or her sex in screen 600 of Fig. 6.) An example of a skipped question would be "Have you ever had sexual contact with another man?" when the donor is female. If, in step 1004, the question should not be skipped, control passes to step 1008.

In step 1008, processor 114 determines whether the respondent wants to display text and graphics associated with the question. The respondent previously indicated his preference using field 504 of Fig. 5 (or by toggling the "display" option as discussed above). As discussed above, the respondent can toggle the "display" option at any time. Therefore, processor 114 frequently checks to see if a toggle has occurred. This check has not been included in the flow charts for ease of explanation. text and graphics are to be displayed, processor 114 executes a "show" function in step 1012 that displays the text and color graphic for the current question on touchscreen 102 (see Fig. 3) and outputs the audio for the question to speaker unit 103. Processor 114 also sets an audiotimer variable to "short". The audiotimer variable is used in steps 1014-1016 to determine when to start accepting input from touchscreen 102 or touchpad 106. the embodiment, when text and color graphics are displayed, it is assumed that the respondent can read the text more quickly than the text is spoken over speaker unit 103. Thus, a short amount of time passes before processor 114 begins accepting input from respondent.

10

15

20

25

30

35

Repeat donors familiar with the questions, also may require a "short" audiotimer until input is accepted. In some embodiments, repeat donors are always given a "short" response time, irrespective of whether text and graphics are to be displayed.

If text and graphics are not to be displayed, processor 114 executes a "hide" function in step 1010 that does not display the text and color graphic for the current question (see Fig. 7) and that outputs the audio for the question to speaker unit 103. Processor 114 also sets an audiotimer variable to "long". In the embodiment, when text and graphics are not displayed, it is assumed that the respondent must wait to hear the question spoken over speaker unit 103. Thus, a relatively long time passes before processor 114 begins accepting input.

In step 1014, processor 114 sets a software audio timer to the value of the audiotimer variable. When the software audio timer expires in step 1016, processor 114 displays buttons on touchscreen 102 (if the "touchscreen" option has been selected) (step 1017). No input is accepted from the selected input device until the software audio time has expired. In the described embodiment, when text and graphics are displayed on the screen, then response buttons 210 are displayed and become active after three seconds of audio. If text and graphics are not visible, then the response buttons are not activated until the end of the audible question.

In step 1018, processor 114 waits for the respondent to touch a button and in step 1020, processor 114 sets the BTN variable to a value representing the button touched by respondent. In step 1022, processor 114 saves the end time in memory 112 or in another storage device. Because the start and end times for the question are both saved, it is possible to determine how long it took the respondent to answer the question (t = TimeEnd - TimeStart). Processor 114 then saves the question number (q), the respondent's response (BTN) (i.e., the

10

15

20

25

30

35

button touched by the respondent), and the amount of time (t) in memory 112 or a storage device. In the described embodiment, processor 114 saves multiple responses, if the respondent repeats questions and gives more than one response. Other embodiments may only save the respondent's last answer.

Fig. 11 shows a format of a data structure used by processor 114 to store user responses for a set of questions (Session,). Information for Session, includes a tag, such as a donor ID and a date and the respondent's responses (ql ... qt). A donor ID can be, e.g., a social security number or a transaction ID number. Each response (q_n) is stored as a question number, the response (possible values include "Yes", "No", "Don't know", or unanswered), and the amount of time it took the respondent to answer the question.

In step 1024, processor 114 determines the flow of control in accordance with the button touched by the respondent (or if the question was skipped because of the sex of the respondent). If the respondent touched a "Back" button, processor 114 displays the prior frame as determined from information in the "Back" field of the state variable described in Figure 12(a) described below. The result of this frame navigation may be to stay at the same question, if there are no previous questions.

If the respondent touched a "Yes", "No", "Don't Know", or "Next" button or if the question is skipped, processor 114 navigates to the next frame determined from information in the respective button fields of the state variable described in Figure 12(a) below. The result of frame navigation, may be to stay at the same question, if the current question is the last question.

The following list contains some examples of questions asked in the described blood donor screening system.

1. Have you read and do you understand the required information about AIDS and associated risk

20

35

factors? Do you understand the blood donation process?

- 2. Are you 17 years of age or older?
- 3. Are you feeling well today?
- 5 4. Do you have active allergy, cold or flu symptoms today?
 - 5. Have you ever: been diagnosed as having AIDS or AIDS related complex (ARC)?
 - 6. Have you ever: had an AIDS (HIV) test that was positive?
 - 7. Have you ever: used any illegal drugs (non-prescribed) by needle, even one time?
 - 8. Have you ever: at any time since 1977, received drugs or money in exchange for sex?
- 9. Have you ever: even one time since 1977 had sexual contact with another man?
 - 10. Have you ever: had bleeding tendencies, clotting disorders or hemophilia? babesiosis?
 - 11. Have you ever: received Factor VIII (AHF), Factor IX or other clotting factors?
 - 12. Have you ever: engaged in sex with a person who has: hemophilia, received Factor VIII, Factor IX, clotting concentrates; used illegal drugs by needle; a diagnosis of AIDS, ARC, AIDS symptoms?
- 25 13. Have you ever: had viral hepatitis, yellow jaundice, liver disease or a positive blood test for hepatitis? Chagas' disease?
 - 14. Have you ever: had chest pains, heart trouble, heart surgery, or a stroke?
- 30 15. Have you ever: had any kind of cancer?
 - 16. Have you ever: had chronic bronchitis, lung disease, persistent cough, shortness of breath or tuberculosis (TB)?
 - 17. Have you ever: had kidney disease or required dialysis?
 - 18. Have you ever: had diabetes? insulin injections?

PCT/US94/09417

WO 95/06296

- 22 -

5

10

15

30

35

19.	Have you	ever:	received human	pituitary	growth
	hormone?	taken	Tegison?		

- Have you ever: had epilepsy, convulsions, seizures or fainting spells?
- In the Past Three Years Have you: lived or 21. traveled outside the U.S.?
 - In the Past Three Years Have you: had malaria, 22. taken antimalarial medication, lived in an area endemic for malaria?
- In the Past Twelve Months Have you: had surgery? 23.
 - 24. In the Past Twelve Months Have you: had a blood transfusion or received blood components?
 - 25. In the Past Twelve Months Have you: had close contact with anyone with hepatitis (family, coworker, friend or health care professional)?
 - 26. In the Past Twelve Months Have you: tattoo, ear or skin piercing, acupuncture or accidental exposure to blood, body fluids, or needlestick?
- 20 In the Past Twelve Months Have you: received 27. Hepatitis B Immune Globulin (HBIG)?
 - 28. In the Past Twelve Months Have you: been a sexual partner of a prostitute? been sexually assaulted?
- 25 29. In the Past Twelve Months Have you: had or been treated for syphilis or gonorrhea?
 - 30. In the Past Twelve Months Have you: exposed or treated for rabies? received rabies?
 - In the Past Six Months Have you: had a serious 31. illness?
 - 32. In the Past Six Months Have you: consulted a doctor?
 - In the Past Six Weeks Have you: been pregnant? 33.
 - In the Past Four Weeks Have you: had any 34. immunizations, inoculations or vaccinations? taken Accutane?

- 23 -

35. In the Past Four Weeks Have you: been exposed to a communicable disease?

- 36. In the Past Three Days Have you: had dental work?
- 5 37. In the Past Three Days Have you: taken any medicine ordered by a doctor?
 - 38. In the Past Three Days Have you: taken any aspirin or products containing aspirin?
 - 39. I believe my blood is safe for transfusion.

In general, for blood donors, these questions may be derived from the American Association of Blood Banks (proposed) standard set, which are derived from regulations of the Food and Drug Administration. Examples of these questions are discussed in Association Bulletin of the American Association of Blood Banks, #92-4, News Briefs, pp 5-7, November/December 1992, which is herein incorporated by reference.

The following list contains a few examples of questions asked in another embodiment of the system for a patient's medical history.

- 1. Have you ever taken medication for emotional problems?
- 2. Have you ever been hospitalized for emotional problems?
- 3. Are you sexually active?

20

25

30

35

4. Has anyone in your immediate family been diagnosed or treated for breast cancer?

The specific questions asked when taking a medical history vary with the purpose of taking the history. A sample medical history is included as Appendix A and is herein incorporated by reference.

Fig. 12(a) shows a format of a data structure for each state in a state machine used by processor 114 to implement the flowcharts of Figs. 9 and 10. The state machine is stored as a table (Fig. 12(b)) or a file in memory 112, where every table entry corresponds to a state S and has the format shown in Fig. 12(a). For each

10

15

20

25

30

35

state, the data structure includes a name of bitmap files for the graphic (field 206) and the picture of the nurse (field 202). The data structure also includes names of files having, respectively, the text of the question (field 204), the label (field 208), and the title (field 207). The data structure also includes a name 1202 of a file having the audio that is to be sent to speaker unit 103 by processor 114. The data structure has a plurality of "state numbers" 1204 to which control passes depending on which button was touched by the respondent ("Yes", "No", "Don't Know", "Back", "Next"). (Skipped questions cause control to pass to the "Next" screen.) addition, the data structure has an indicator variable for whether a question applies only to females (F), males (M) or to both sexes (B).

- 24 -

III. Other Embodiments

Other embodiments of the invention solicit other types of confidential information. For example, the blood donor system described above can be used to ask other types or confidential questions, such as questions to screen plasma donors, questions relating to a medical history, employment experience, or questions related to eligibility for public assistance of the respondent. All that is necessary to adapt the system for a different set of questions is to change the text files containing the questions or change the graphics associated with the questions. In some embodiments of the invention, the order of the questions changes depends on the responses To implement this feature, the values of state machine table of Fig. 12(b) would have to be changed. format used by the state machine would not have to change, but could change depending on the application. example, if a respondent answers "Don't Know", a next state may be a first in a series of questions that attempt to obtain a clearer response. In contrast, if the response to the same question is "Yes", processor 114 may

display and output to the speaker a completely different line of questions.

5

10

15

20

25

Other embodiments of the invention use full motion video instead of a static picture and graphics. For example, the static picture of a nurse in field 302 of Fig. 3 could be replaced with a moving picture of a nurse. In such an embodiment, full motion video preferably would be achieved through use of Microsoft Video for Windows, where the data required for the moving image is stored in a file or series of files as described in the Microsoft Video for Windows User's Guide available from Microsoft Corporation, which is herein incorporated by reference. Alternately, the picture in field 306 of Fig. 3 could be a full motion video picture or a third window containing full motion video could be added to a screen.

In yet another embodiment of the invention, a video camera is added to the system of Fig. 1 (or a similar system). Processor 114 displays a screen (not shown) that asks the respondent to step into a predetermined area and processor 114 activates the video camera to record a video record of the respondent in memory 112 or some other storage medium. Yet another embodiment allows the respondent to sign his or her name on monitor 101 through use of "pen technology." Processor 114 reads respondent's signature from touchscreen 102 and stores a graphic representation of the signature in a storage device. Such an embodiment could also use a light pen as an input device.

Another embodiment solicits identification data from
the respondent. This data can be a social security number
or ID number entered by the respondent via
touchscreen 102, touchpad 106, or a keyboard, or by
inserting a magnetic card in a magnetic card reader.
Alternately, the system may assign an arbitrary ID to the
respondent and associate the ID with the respondent's name
stored in a separate file.

10

15

20

25

30

35

In another embodiment processor 114 displays a screen showing a medical "informed consent" form. In this embodiment, the respondent cannot skip the screen, but must touch a button on the screen (or some alternate input device) indicating that he has read and understood the consent form and that he has given his consent for the medical procedure mentioned in the form. In this embodiment, the consent form may be too long to fit in the window, and processor 114 scrolls the text of the consent form within the window in response to buttons touched by the respondent. In this embodiment, the user must scroll through the entire form before being allowed to enter a response because it is important to be; able to draw an inference that the respondent has read the consent form.

In yet another embodiment, a processor 114 displays another screen (similar to that of Fig. 6) that allows the respondent to indicate whether this is the first time he has given responses to the questions (e.g., if he is a first time blood donor). If the respondent has never answered the questions before, processor 114 displays a series of complex questions and requires the respondent to wait several seconds before answering. If the respondent has seen the questions before, processor 114 displays a series of shorter questions, and allows the respondent to answer after a shorter period of time. This embodiment requires that the state table of Figs. 12(a) and 12(b) indicate two transition states for each button: one transition state for new donors and one for repeat donors.

In yet another embodiment, buttons 210 include a "Pause/Play" button that allows the respondent to pause and restart (play) the two questions. Some embodiments have background music or some type of background audio playing while waiting for a response from the respondent. The Pause button allows the respondent to pause the background music. Yet another embodiment of the invention includes a keyboard as an input device. Yet another embodiment of the invention includes a mouse or stylus

10

15

20

25

30

35

that moves a cursor on a screen as an input device. Yet another embodiment of this invention includes a bar code or magstripe reader as an input device.

Other embodiments of the invention store, retrieve and check a networked central database of the names of respondents that have been deferred or that have been identified as troublesome or litigious patients. These embodiments request that the respondent enter their name or their ID code. If processor 114 finds the name or ID code in the central database, processor 114 identifies the respondent as a potentially troublesome respondent. For example, the database could keep track of whether respondents who have been deferred before, who have the HIV virus, who have syphilis, malaria, or other diseases or positive results on laboratory tests, or who have sued other doctors or hospitals. As described above, previous responses also can be compared to current responses as a part of the decision rule.

In another embodiment, after all the responses have been gathered, processor 114 sends the responses to a central computer system over a modem, where the responses are stored in a central database.

Alternately, the central computer stores a database of troublesome respondents. If the central computer determines that the respondent is a potentially troublesome respondent, then a warning signal is sent back to processor 114, and processor 114 prints or displays a warning message.

IV. Summary

The present invention solicits responses to confidential questions and allows a respondent to select a degree of privacy with which he feels most comfortable by allowing the respondent to control volume of a speaker, whether audio is output through a speaker or through a handset, whether text and graphics associated with the question are printed on the display or not, whether a touchscreen or a more private input device are used, and

- 28 -

whether responses are echoed audibly. The invention also eliminates transcription and key entry errors and interviewer bias and makes the system easy to update and change. The questions are presented in a consistent manner, and can ensure that all questions are answered.

5

10

Other embodiment s will be apparent to those skilled in the art from consideration of the specification and practice of the invention disclosed herein. It is intended that the specification and examples be considered as exemplary only, with a true scope of the invention being indicated by the following claims.

APPENDIX A

			Patient, please <u>do not</u> write in this
FOOD AND FLUID INTA	\KE		space.
	Yes	No	Nursing Assessment of Nutrition:
Are you on a special diet?			
(Include TPN). If yes, explain			
Have you had any recent weight change?	_		
Do you wear dentures or use a bridge?		—	,
Are you experiencing any of the following? Nausea/Vomiting			
Smell or taste changes		_	
Difficulty swallowing			
Mouth sores			
BOWEL AND BLADDER H	ABITS		
	Yes	No	Nursing Assessment of Bowel and Bladder
Do you have a current or past history of			Function:
constipation, diarrhea, or difficulty controlling		İ	
urine and/or stool?			
If yes, describe what you do for each,	_		
100			
When was your last bowel movement?	-		
Do you have an ostomy? If yes, describe	_		
What supplies do you use?	-		
verial supplies do you use:	-		
	-		
BREATHING AND CIRCUL	ΔΤΙΩΝΙ		
biolining and cheep	Yes	No	Nursing Assessment of Respiratory and
Are you experiencing or have you experience		140	Cardiovascular Function:
any of the following in the past?	-	-	
Chest Pain			
Palpitations	******		
Shortness of breath			
Wheezing			
Swelling in arms or legs			
Cold hands or feet			·
Coughing Dizziness	_		
Fainting	_		
Numbness/pain in arm(s)		-	
<u> </u>	_	_	
Do you smoke?	_		
If yes, how much?			
		ŀ	
THINKING AND REMEMB			
	Yes	No	Nursing Assessment of Thought Processes:
Have you had any difficulty thinking or			-
concentrating?			
If yes, describe			
Have you noticed any problems with your	•		
		ŀ	
memory?	_		

ACTIVITY AND REST			
Do you need help with activities such as eating, bathing, dressing, writing or walking? If yes, describe	Yes	No —	
Do you use a prosthesis? Have you fallen within the past 6 months? Has illness or treatment affected your daily activities?	_	_	Patient, please <u>do not</u> write in this space. Nursing Assessment of Self-Care and Mobility:
Home Work activities Finances Caring for children/parents/others Leisure/Recreation/Socializing		_	Is the patient at risk for falls? Yes No
How often does fatigue interfere with your norma activities?NeverSometimes Do you have any problems sleeping? Do you use anything to help you sleep? If yes, describe		Niways	
PAIN	Yes	No	Nursing Assessment of Pain: Include the following:
Have you had persistent or frequent pain during the past 2 weeks? Have you received treatment for pain during the past 2 weeks?			Location(s):
Answer <u>ONLY</u> if you are <u>receiving treatment</u> for pain:			Intensity: (0-10)
Does your treatment control your pain most of the time?		_	Quality:
Are you satisfied with the relief you obtain from paint treatment?		_	Onset:
Mark the areas of your pain.			Duration:
			Precipitating Factors:
			Relieving Factors:
			Breakthrough pain: Yes No
<u> </u>			If yes, frequency
			precipitating factor
Memorial Sloan-Kettering Cancer Center 1275 York Avenue, New York, New York 10021			

CTNICEC			Patient, please do not write in this
SENSES	Yes	No	space. Nursing Assessment of Sensory Perceptions:
Have you noticed any changes in the following? Seeing/Reading Hearing/Speaking	, 		
Do you have a numbness/tingling? Do you use: (Circle) Glasses/Contact Lenses/Hearing Aid(s)? Which of the above did you bring with you?			
SKIN	Yes	No	Nursing Assessment of Skin: Gosnell Scale
Have you noticed any of the following? Changes in the skin	_	_	Mental Status: Continence Mobility: Activity: Nutrition:
Wounds or sores			1. Alert 1. Fully 1. Full 1. Ambulatory 1. Good Controlled 2. Anabash: 2. Usually 2. Slightly 2. Walks with 2. Fair
Bruises			Controlled Limited Assistance 3. Confused 3. Minimally 3. Very 3. Poor 3. Poor
	_		A. Stuporous 4 Absence of Control 4. Immed 4. Bedfast Control
Dryness or itching	_		5. Unconscious Total score
Rashes			Circle appropriate # and tally score. A score of 10-20 indicates at risk for pressure ulcer. Describe condition of skin:
Do you have any of the following: Catheters Ports Pumps Shunts Ommaya When was it inserted? Why is it used? Who takes care of it?	Yes	No	Catheter: Type Shunt: Type Other: Type Indicate the vein, artery, or body cavity that the catheter/port/pump enters,

			Patient, please do not write in this		
COPING					
†	Yes	No	space. Nursing Assessment of Coping/Feelings:		
What has helped you cope with difficulties in		jj.	Maising Assessment of Coping/Feemigs.		
the past?			1		
Talking with spouse, friend, etc.			ղ լ		
Talking with a psychiatrist or counselor			1		
Medication to relieve stress			1		
Exercise/Hobbies			N I		
Smoking/Alcohol/Drugs					
Religion (specify)			1		
Relaxation technique		_			
Joining a group		— I	1		
Other (specify)			N i		
With whom can you share your problems and fe	elinas?	, i i	[[
	yw 1		N I		
Name:Relationship:		·	<u> </u>		
(Aciduoisinp		•	[[
	Yes	No	Į į		
Have you ever taken medication for emotional	•				
problems?					
			1		
Have you ever been hospitalized for emotional			[] .		
problems?			'l		
If yes when?			\ 		
reason?			 		
			1		
Have you ever attempted or planned suicide?					
_			1		
FEELINGS		ļ	V		
	Yes	No	Assessment of Need for Referral:		
For each statement, consider how you have			, about the troop of troising.		
been feeling:			11		
I no longer enjoy the things I used to.			\		
I cry more than I used to.			11		
I feel:			lli		
Sad/depressed	_		₩		
Anxious		_	HI		
Hopeless			111		
Forgetful	_		111		
Confused/disoriented	_		III.		
Guilty					
Dependent Suisidel	_		lli		
Suicidal	· —		₩.		
I have experienced changes in my					
appearance that are troubling me. I have experienced changes in my					
sexual desire or activity that are					
troubling me.			11		
troubling me. I would like a referral to the:	_		N		
Chaplain Psychiatric Nurse Clinician			11		
Psychiatrist Social Worker			III		
Fayonathat Goolal Worker					
Memorial Sloan-Kettering Cancer Cente	r		W ·		
1275 York Avenue, New York, New York 10021					

			Patient, please do not write in this
HEALTH PRACTICES			space.
	Yes	No	^
Are you sexually active?			
If yes, do you use contraceptives?			
For females: Indicate date of last menstrual period?			
DISCHARGE PLANNIN	G Yes	No	
Do you live in an apartment or a house?		,,,	
Will stairs present a problem?		_	tit nations in consistent community halp
With whom do you live?	-		*If patient is receiving community help, document the agency used on the Ongoing Discharge Plan.
How many children do you have?	_		
What are their ages?	_		Referred to Social Work Dept. Yes No
Who could help you at home if you need help?	? -		TENTATIVE DISCHARGE PLAN
Are you currently receiving help from a community agency?			
If yes, what is the name? Are you currently receiving help from an			
ambulatory care unit?	_	_	
If yes, from whom?			
Are you responsible for the care of anyone else of the second of the sec	e?		RN
Do you think you will need help when you go	• 1		Signature of nurse
home?	_		
			Date Time
Signature of patient		—	
= -			111
or			
			H
	. 		
Signature of other (please specify relationship)		

- 35 **-**

WHAT IS CLAIMED IS:

5

15

25

30

35

1. A system for gathering confidential data from a human respondent, comprising:

a display device;

means for presenting the respondent with two privacy alternatives that relate to a manner in which a response should be solicited;

means for receiving an input from the respondent choosing one of the privacy alternatives;

means for soliciting, via the display device in accordance with the chosen privacy alternative, the response; and means for receiving a response from the respondent.

2. The system of claim 1, wherein the soliciting means includes:

means for printing a textual question on the display device when the response is solicited, in accordance with a first privacy alternative chosen by the respondent; and

means for leaving the textual display blank on the display device when the response is solicited, in accordance with a second privacy alternative chosen by the respondent.

3. The system of claim 1, wherein the soliciting means includes:

means for displaying a graphic image corresponding to a current question on the display device when the response is solicited, in accordance with a first privacy alternative chosen DN, by the respondent; and

means for displaying a graphic image corresponding to a current question on the display device when the response is solicited, in accordance with a second privacy alternative chosen by the respondent.

4. The system of claim 1, further including means for storing the received response.

5

10

15

20

25

30

35

- 5. The system of claim 1, further including means for sending the received response to a second system via a modem.
- 6. The system of claim 1, further including means for making a decision on a status of the respondent in accordance with the received response.
 - 7. The system of claim 1, further including means for asking the respondent to indicate a display language and means for soliciting the response in an indicated display language.
 - 8. The system of claim 1, further including means for determining a characteristic of the respondent.
 - 9. The system of claim 8, wherein the means for determining a characteristic of the respondent includes:

means for determining the gender of the respondent; and

means for skipping the solicitation of the response in accordance with the determined gender.

- 10. The system of claim 9, wherein the means for determining the gender of the respondent includes means for asking the respondent to indicate a gender.
- 11. The system of claim 8, wherein the means for determining a characteristic of the respondent includes means for determining a new/repeat donor status of the respondent.
- 12. The system of claim 1, wherein the solicitation means includes means for displaying a picture of a human being on the display screen.
- 13. The system of claim 1, wherein the solicitation means includes means for displaying a full motion video picture on the display screen during solicitation.
 - 14. The system of claim 1, further including means for displaying an indicator on the display screen that allows the respondent to repeat a previous solicitation.
 - 15. The system of claim 1, further including means for allowing the respondent to give a response only from a

-37 **-**

predetermined set of responses but also allows free form input via keyboard, pen or other device.

16. The system of claim 1, further including an audio speaker and means for changing the volume of the audio speaker.

5

30

35

- 17. The system of claim 1, further including means for inputting and storing a signature of the respondent.
- 18. The system of claim 1, further including means for inputting and storing a video image of the respondent.
- 19. The system of claim 1, further including means for asking a predetermined series of questions when the respondent's response is "don't know" that is different from questions asked 'when the response is other than "don't know".
- - 21. The system of claim 1, further including means for soliciting and receiving identification data from the respondent identifying the respondent.
- 22. The system of claim 21, further including:

 a central computer having a database containing identification data for respondents having predetermined characteristics; and

means, connected to the central computer, for making a decision on a status of the respondent in accordance with the received identification data and stored identification data from the database.

23. The system of claim 1, further including:

means for determining a time since a last blood
donation of the respondent, where blood donation includes
one of whole blood donation, plasma donation, and platelet
donation; and means for making a decision on a status of

- 38 -

the respondent in accordance with the time since last blood donation.

5

The system of claim 1, further including: means for making a decision on a status of the respondent in; and

an output device for displaying the decision of the system regarding the status of the respondent, thus allowing for human oversight of the decision.

The system of claim 1, wherein the solicitation 10 means includes:

means for asking a question relating to blood donation criteria; and

means for receiving a response from the respondent.

The system of claim 1, wherein the solicitation 15 means includes:

means for asking a question relating to medical history taking; and

means for receiving a response from the 20 respondent.

- The system of claim 1, further including means for measuring a time period that the respondent pauses before responding and means for using the measured time period to determine a status of the respondent.
- 25 A system for gathering confidential data from a human respondent, comprising:

an audio output device;

means for allowing the respondent to adjust the volume of the audio output device;

means for presenting the respondent with two 30 privacy alternatives that relate to a manner in which a response should be solicited;

means for receiving an input from the respondent choosing one of the privacy alternatives;

means for soliciting, via the output device in 35 accordance with the chosen privacy alternative, the

- 39 **-**

response; and means for receiving a response from the respondent.

29. A system for gathering confidential data from a human respondent, comprising:

a first input device;

a second input device;

means for displaying two privacy alternatives that relate to the first and second input devices;

means for receiving an input from the respondent choosing one of the privacy alternatives;

means for soliciting a response from the respondent; and

means for receiving a response from the respondent via one of the first and second input devices in accordance with the chosen privacy alternative.

- The system of claim 29 wherein the first input device is a touchscreen and the second input device is a touchpad or key board.
- A system for gathering confidential data from a 20 humane respondent, comprising:

an audio output device;

means for receiving an input from the respondent indicating a desired degree of privacy during questioning; means for soliciting the respondent for a

25 response;

5

10

15

30

means for receiving a response from the respondent; and

means for echoing the response via the audio output device when the respondent indicates a predetermined degree of privacy.

A system for gathering confidential data from a human respondent, comprising:

an audio output device having a handset and a loudspeaker;

means for allowing the respondent to indicate a 35 privacy alternative relating to whether a response is solicited via the handset or the loudspeaker;

- 40 **-**

means for soliciting, via the audio output device in accordance with the indicated privacy alternative, the response; and

means for receiving a response from the 5 respondent.

- 33. A system for gathering confidential data from a potential blood donor, comprising:
 - a display device;

means for presenting the potential donor with

two privacy alternatives that relate to a manner in which
a response relating to blood donation criteria should be
solicited;

means for receiving an input from the potential blood donor choosing one of the privacy alternatives;

- means for displaying a textual question and a graphic image associated with a question relating to blood donation criteria on the display device when the response is solicited, in accordance with a first privacy alternative chosen by the potential donor; and
- means for leaving the textual display and graphic image blank on the display device when the response is solicited, in accordance with a second privacy alternative chosen by the potential donor.
- 34. A system for gathering confidential data from a potential blood donor, comprising:
 - a display screen;

means for privately receiving audio information;

- a display screen;
- a handset device;

35

30 means for receiving an input from the potential donor indicating a desired degree of privacy during questioning;

means for displaying a question relating to blood donation criteria on the display screen when the potential donor indicates a first degree of privacy;

-41 -

means for asking the question via the handset device when the potential donor indicates a second degree of privacy; and

means for receiving a response to the question from the potential donor.

- 35. A system for gathering confidential data from a potential blood donor, comprising:
 - a touch screen;
 - a touchpad;

20

25

30

10 means for receiving an input from the potential donor indicating a desired degree of privacy during questioning;

means for asking the potential donor a question relating to blood donation criteria;

means for receiving a response to the question from the potential donor via the touch screen when the potential donor indicates a first degree of privacy; and

means for receiving a response to the question from the potential donor via the touchpad when the potential donor indicates a second degree of privacy.

36. A system for gathering confidential data from a potential donor, comprising:

an audio output device;

means for receiving an input from the potential donor indicating a desired degree of privacy during questioning;

means for asking the potential donor a question relating to blood donor criteria;

means for receiving a response to the question from the potential donor; and

means for echoing the response via the audio output device when the potential donor indicates a predetermined degree of privacy.

- 37. A system for gathering confidential data from a potential blood donor, comprising:
 - a touch screen;
 - a touchpad;

5

10

15

20

an audio output device, including a loudspeaker
and a handset;

means for receiving an input from the potential donor indicating a desired degree of privacy during questioning;

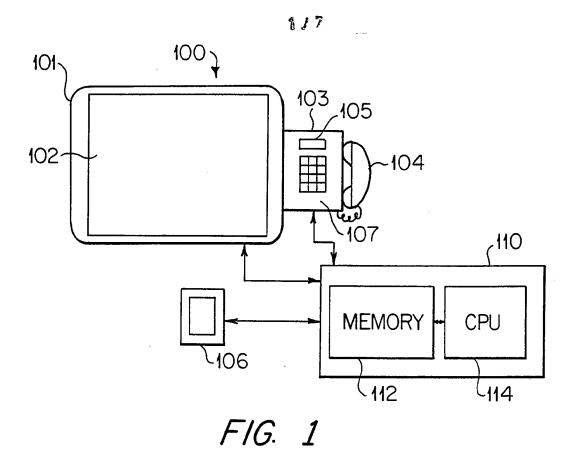
means for asking the potential donor a question relating to blood donor criteria, using one of the loudspeaker and the handset in accordance with the desired degree of privacy, and displaying or not displaying the question on the touchscreen in accordance with the desired degree of privacy;

means for receiving a response to the question from the potential donor via the touch screen when the potential donor indicates a first degree of privacy;

means for receiving a response to the question from the potential donor via the touchpad when the potential donor indicates a second degree of privacy; and

means for echoing or not echoing the response via the output device in accordance with the desired degree of privacy.

38. The system of claim 1, further including an audio output device having a headset that operates in a hands-free manner.



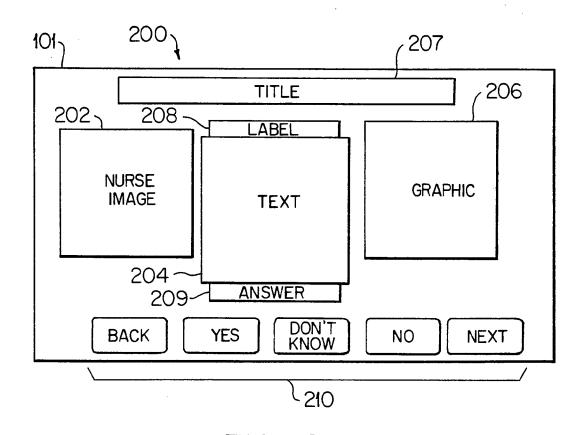


FIG. 2

SUBSTITUTE SHEET (RULE 26)

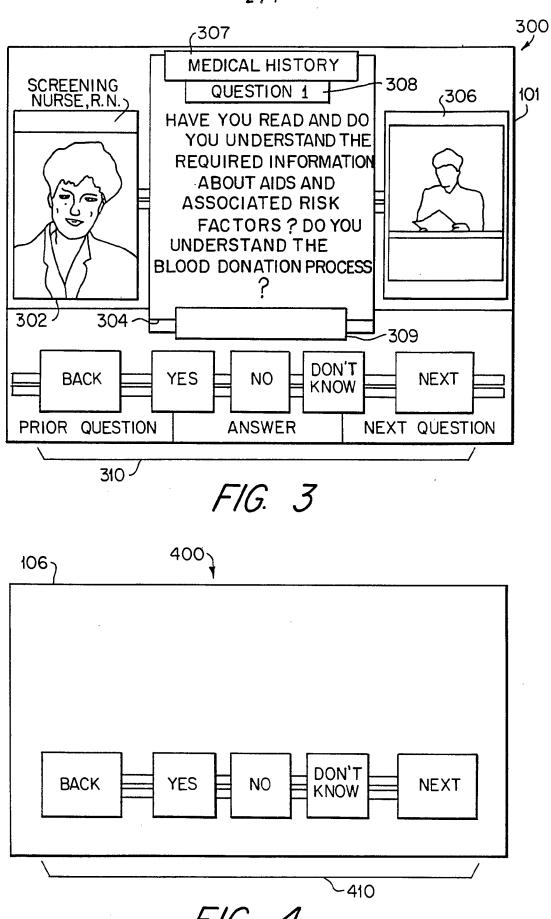


FIG. 4

SUBSTITUTE SHEET (RULE 26)

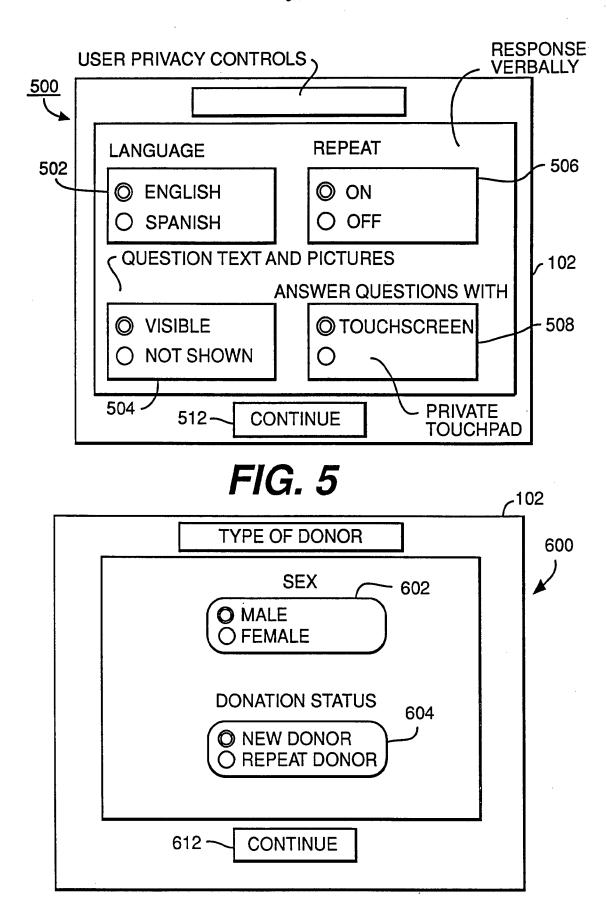
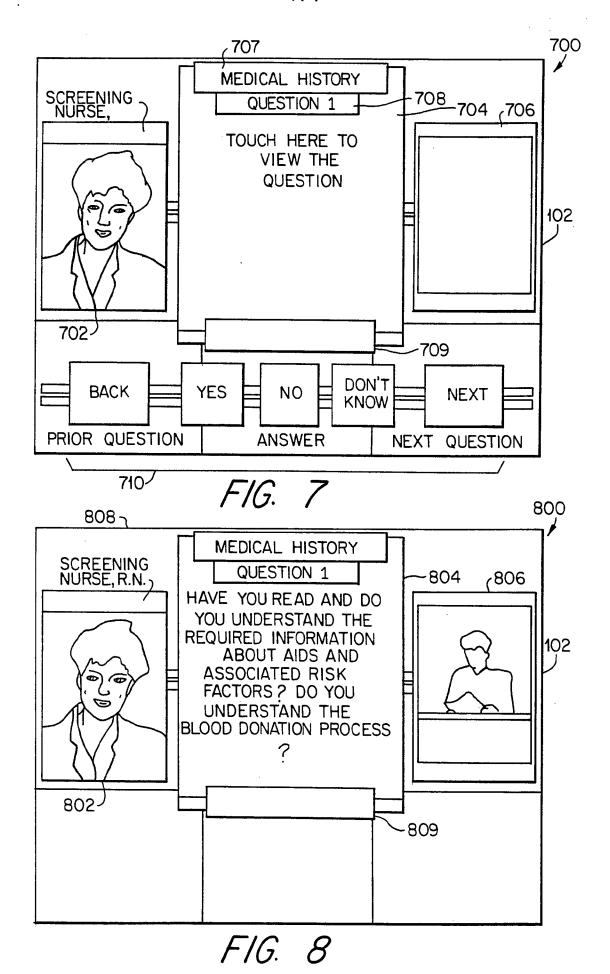
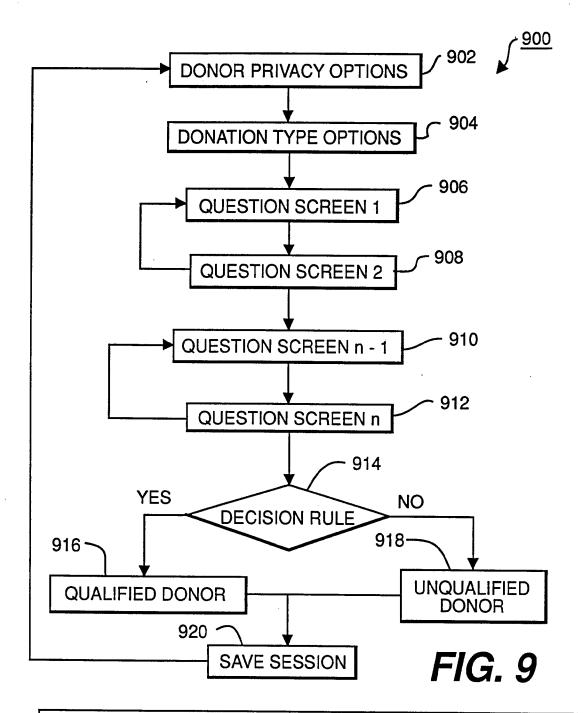


FIG. 6

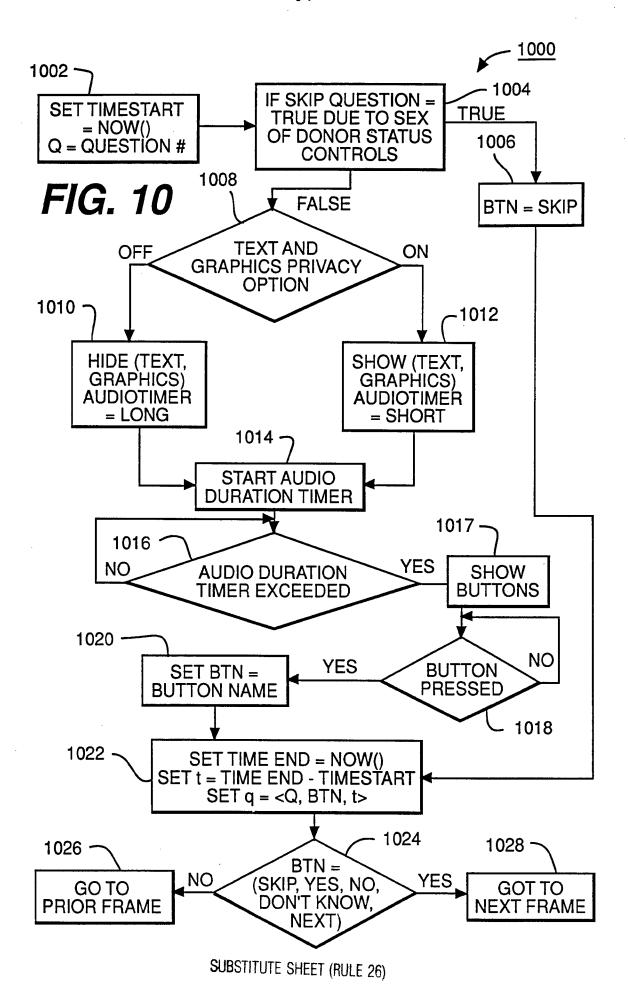


SUBSTITUTE SHEET (RULE 26)



DATA STRU	CTURES
TAG qi SESSION n	= <donor date="" id,=""> = <question#, respone="" response,="" time=""> = <tag, q1,="" q2,,qt=""></tag,></question#,></donor>
DECISION F	RULE
(YES/NO)	FUNCTION(SESSION n ,SESSION n-1)

FIG. 11



<s 1, graphic. bmp, text. asc,nurseimg.bmp(avi),text.wav, YES, NO, DON'T KNOW, BACK, NEXT, LABEL, TITLE, SEX> State 1 =

WHERE THE FIELDS OF THE STATE CONTROL ARE

nurseimg.bmp text.wav YES NO DON'T KNOW BACK NEXT LABEL TITLE SEX graphic, bmp text, asc <u>0,+,0,€</u> 204 -1202 / 202 1204~ 208

STATE NUMBER.

NAME OF FILE FOR THE GRAPHIC IMAGE.

NAME OF FILE FOR THE QUESTION TEXT.

NAME OF FILE FOR THE QUESTION TEXT.

NAME OF FILE WITH THE AUDIO ACCOMPANYING THE QUESTION.

STATE NUMBER TO TRANSITION TO IF THE YES BUTTON IS CHOSEN.

STATE NUMBER TO TRANSITION TO IF THE BACK BUTTON IS CHOSEN.

STATE NUMBER TO TRANSITION TO IF THE BACK BUTTON IS CHOSEN.

STATE NUMBER TO TRANSITION TO IF THE BACK BUTTON IS CHOSEN.

STATE NUMBER TO TRANSITION TO IF THE NEXT BUTTON IS CHOSEN.

TEXT OF THE FRAME LABEL.

TEXT OF THE FRAME TITLE.

SEX PERTAINING TO M - MALE ONLY, F - FEMALE.

s ₁ (STATE ₁) s ₂ (STATE ₂)	• •	s _n (STATE _n)	
--	-----	--------------------------------------	--

FIG. 12(b)

SUBSTITUTE SHEET (RULE 26)

A. CLASSIFICATION OF SUBJECT MATTER IPC 6 G06F19/00 According to International Patent Classification (IPC) or to both national classification and IPC **B. FIELDS SEARCHED** Minimum documentation searched (classification system followed by classification symbols) IPC 6 G06F Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Category ' Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. A US,A,5 201 034 (M.MATSUURA ET AL, JP) 6 1-38 April 1993 see column 1, line 31 - line 60 see column 3, line 48 - column 5, line 30 see column 6, line 23 - line 40 P,A EP, A, O 583 896 (FUJITSU LIMITED, JP) 23 1-38 February 1994 see column 2, line 5 - column 3, line 8 see column 7, line 30 - column 12, line 53 Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents: To later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the 'A' document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to filing date 'L' document which may throw doubts on priority claim(s) or involve an inventive step when the document is taken alone which is cited to establish the publication date of another "Y" document of particular relevance; the claimed invention citation or other special reason (as specified) cannot be considered to involve an inventive step when the document is combined with one or more other such docu-"O" document referring to an oral disclosure, use, exhibition or other means ments, such combination being obvious to a person skilled document published prior to the international filing date but in the art. later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report **0** 6. ot. 95 22 December 1994 Name and mailing address of the ISA Authorized officer European Patent Office, P.B. 5818 Patentiaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Barba, M Fax: (+31-70) 340-3016

1

Information on patent family members

PCT/US 94/09417

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
US-A-5201034	06-04-93	JP-A-	2093718	04-04-90
EP-A-0583896	23-02-94	JP-A-	6052398	25-02-94